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PROFESSION

K. Barton Farris, MD, right, a delegate for the Louisiana State Medical Society, argues against a proposed amendment during a floor debate on the national drug shortage policy. Joseph J. Fallon Jr., MD, an endocrinologist from Marlton, N.J., waits for his turn to speak. [Photo by Ted Grudzinski / AMA]

AMA delegates detail steps to confront national drug shortage emergency

The AMA house backs such recommendations as mandating public notification of market withdrawals up to a year in advance.

By KEVIN B. O'REILLY, amednews staff. *Posted Nov. 28, 2011.*

New Orleans -- The AMA House of Delegates said the rising number of critical drug shortages constitutes a "national public health emergency" that requires a swift and sophisticated response to address the complex roots of the crisis.

The tally of drugs classified as being in shortage by the Food and Drug Administration tripled from 61 in 2005 to 178 in 2010. Nearly three-quarters of the shortages involved sterile injectables, and 80% of the shortage drugs are generics. More than half of drug shortages are due to manufacturing quality problems, the FDA says.

The agency's figures may underestimate the extent of the problem. The FDA counts a drug as being in shortage only if it is "medically necessary," meaning that there is no other source of the drug or adequate substitute -- even if the alternative is available only after delays or imposes higher costs on patients, hospitals or doctors.

Using a broader definition that includes any drug whose supply is interrupted, the American Society of Health-System Pharmacists lists more than 200 current drug shortages. These are in addition to more than 80 shortages that have been resolved in 2011.

"Our patients are suffering, unable to receive the vital medicines that they need," said Leah S. Mc Cormack, MD, a Forest Hills, N.Y., dermatologist who spoke on behalf of the Medical Society of the State of New York in house reference committee testimony. "The patients of America need to hear from the physicians of America that this is an emergency. We really need the concrete steps on how to solve this problem."

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At its November Interim Meeting, the house backed the recommendations of a 2010 summit convened by organizations representing pharmacists, oncologists, anesthesiologists and medication-safety experts. These include:

- Requiring public notification of market withdrawals up to a year in advance.
- Changing the FDA definition of a "medically necessary" drug in shortage to expand the agency's authority to act.
- Offering tax incentives to manufacturers that produce critical drugs or upgrade the quality of their practices to prevent supply

disruptions.
- Requiring confidential notification to the FDA when there is a sole manufacturing facility for a drug.

Delegates directed the AMA to advocate that the FDA or Congress require drugmakers to establish a continuity plan for supplying vital and life-sustaining medications and vaccines. The house also asked the AMA Council on Science and Public Health to report back at the June 2012 Annual Meeting on progress in preventing drug shortages, especially in oncology.

The house rejected a proposal made on the floor to call for eliminating Medicare's average sales price formula, which some experts argue is to blame for the rise in drug shortages. Delegates also voted down a measure that would have sought to penalize drug manufacturers that fail to remedy a shortage within 30 days. Financial penalties, if enacted, would discourage entry into a generic-drug market with slim profit margins, said Louisiana State Medical Society delegate K. Barton Farris, MD.

"This would only exacerbate the problem," said Dr. Farris, a specialist in anatomic and clinical pathology from Marrero, La.

Officials in Washington have taken some action on the matter. Bills proposed in the House and Senate would require drugmakers to notify the FDA of any anticipated supply disruptions six months in advance.

On Oct. 31, President Obama issued an executive order directing the FDA to ask drugmakers voluntarily to provide information about interruptions, delays, production or import problems or unexpected increases in demand that might lead to shortages. Obama also told the FDA to expedite reviews of critical drug suppliers and manufacturers and ordered the Justice Dept. to investigate price-gouging of shortage drugs.

Specialty pharmaceutical distributors have come forward to meet the demand for shortage drugs on the so-called gray market. The extent of the markup on the drugs is disputed, but a June American Hospital Assn. survey found 92% of hospitals reporting higher drug costs due to shortages.

Impact on physicians, patients

Although shortages affect only a sliver of the drugs used in the U.S. -- 1% or less, according to an October Dept. of Health and Human Services report -- they can hit physicians and their patients hard, delegates said. Oncology and anesthesiology medicines have been especially affected by the crisis.

"For anesthesiologists across the country, this is an ongoing problem," said Alvin C. Head, MD, a delegate from Augusta, Ga., who spoke on behalf of the American Society of Anesthesiologists in reference committee testimony.

"I consider this a patient safety issue, as the substitute drugs are not always equivalent," he said.

In addition to delays in care and higher costs, shortages have led to harmful mix-ups, according to the council report the house adopted. For example, when morphine was in shortage, intravenous hydromorphone was substituted in its place. But in some cases the drug was incorrectly prescribed at the intended morphine dose, leading to at least two patient deaths.

During an Interim Meeting education session on the shortage crisis, American Society of Clinical Oncology delegate Johannes C. Nunnink, MD, of Colchester, Vt., described cases where he has had to delay care or substitute much more expensive drugs that financially burdened patients faced with 20% co-payments.

"The bottom line is: When you're sitting down with a patient talking about the standard regimen of treatment, you have to spend the extra time to check and say, 'Oh, we don't have Taxol,' " said Dr. Nunnink, referring to the brand name for paclitaxel, an injectable drug used to treat ovarian cancer. "To have that discussion with the patient is incredibly frustrating."

Jane C. Fitch, MD, an American Society of Anesthesiologists delegate from Oklahoma City, also has seen the shortages' effect.

"We have had patients in the operating rooms longer than necessary, and in recovery rooms longer than needed, and we've had significant patient satisfaction issues," Dr. Fitch said. "We have been dealing with this problem for the last decade and more acutely in the last five years. We appreciate any weight the AMA can throw behind this. It really is our patients who suffer."

ADDITIONAL INFORMATION:

Where the shortages are

More than 80% of the drugs in shortage are generics. The vast majority are injectables that require dedicated manufacturing lines and are more susceptible to manufacturing problems. Nearly 30% of shortage drugs between 2006 and 2011 fall into a broad category that includes anti-clotting agents and immunosuppressants.

Therapy area	Percentage of all shortage products
Oncology	16%

Anti-infectives	15%
Cardiovascular	12%
Central nervous system	11%
Pain	9%
Vitamins, minerals	9%

Source: "Drug Shortages: A closer look at products, suppliers and volume volatility," IMS Institute for Healthcare Informatics, November (**www.imshealth.com/drugshortages**)

How shortages harm patients

Drug shortages have delayed care and led to harmful medication errors. Here are some examples of reported problems:

Antibiotics: A patient with *Pseudomonas* infection sensitive only to amikacin died when the drug was unavailable.

Chemotherapy: Prediluted methotrexate was unavailable. A vial of drug powder was reconstituted incorrectly, so the patient received too small a dose.

Neuromuscular blockers: Cancellation of surgeries and procedures.

Morphine: Administered 10 mg/mL that was on hand instead of the typical 1 mg/mL. The patient required naloxone and was transferred to critical care.

Propofol: Wrong dosing rates used with dexmedetomidine or midazolam alternatives, leading to overdose.

Source: "Drug shortages: National survey reveals high level of frustration, low level of safety," *ISMP Medication Safety Alert Acute Care*, Sept. 23, 2010 (**www.ismp.org/newsletters/acutecare/articles/20100923.asp**)

Meeting notes: Legislative actions

Issue: The long-term viability of Medicare is a concern for all Americans. Spending projections suggest that the program is on an unsustainable path, and the failure to repeal the sustainable growth rate formula has compounded budget problems.
Proposed action: The Council on Medical Service recommends that the AMA develop a report on Medicare reform strategies for the June 2012 Annual Meeting. *[Adopted]*

Issue: Medicare and Medicaid are using recovery audit contractors to uncover improper payments to physicians and hospitals. Contractors have scoured years of paid claims to find overpayments and recoup hundreds of millions of dollars.
Proposed action: Direct the AMA to monitor Medicare and Medicaid RAC practices and recovery statistics. The Association should encourage the Centers for Medicare & Medicaid Services to penalize RACs that engage in abusive behaviors. *[Adopted]*

Issue: A Florida law prohibited doctors from asking patients about gun ownership. The law was overturned by a federal judge, but doctors have concerns about efforts to prohibit discussions about firearm safety.
Proposed action: Oppose restrictions on physicians being able to inquire and talk about firearm safety issues with their patients. The AMA also would oppose laws limiting physicians' discussions. *[Adopted]*

Issue: Some communities have tried to ban infant male circumcision and have questioned the health benefits of the surgery. Doctors have argued that a physician's clinical judgment and informed decisions of parents should not be impeded.
Proposed action: Oppose any attempt to prohibit male infant circumcision. *[Adopted]*

Issue: Medicare program auditors are moving to review electronic medical records due to concerns about billing systems that overvalue services. Cloning of patient data on subsequent visits, "auto-fill" functions and other EMR features could lead to improper payments to physicians, Medicare officials have said.
Proposed action: Direct the AMA to lead an effort with CMS to set guidance for entities auditing EMR documentation. *[Adopted]*

WEBLINK

Food and Drug Administration's drug shortages website (**www.fda.gov/drugs/drugsafety/drugshortages**)

American Society of Health-System Pharmacists Drug Shortages Resource Center (**www.ashp.org/drugshortages**)

"Buyer beware: Drug shortages and the gray market," Premier Inc., August (**www.premierinc.com/about/news/11-aug/Gray-Market/Gray-Market-Analysis-08152011.pdf**)

"Economic Analysis of the Causes of Drug Shortages," Dept. of Health and Human Services' Office of the Assistant Secretary for Planning and Evaluation, October (**aspe.hhs.gov/sp/reports/2011/drugshortages/ib.shtml**)

Thomas, the federal legislative information service, for bill summary, status and full text of the Preserving Access to

Life-Saving Medications Act, S 296 and HR 2245 (**thomas.loc.gov**)

"Drug Shortages: A closer look at products, suppliers and volume volatility," IMS Institute for Healthcare Informatics, November (**www.imshealth.com/drugshortages**)

"Drug shortages: National survey reveals high level of frustration, low level of safety," ISMP Medication Safety Alert Acute Care, Sept. 23, 2010 (**www.ismp.org/newsletters/acutecare/articles/20100923.asp**)

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